GENERAL MILLS

July 10th, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: [Docket No. FDA-2012-N-0495] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars; (OMB Control Number 0910-New) Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats and Declaration of Amount of Added Sugars--78 Federal Register 32394, May 30, 2013.

Dear Sir/Madam:

General Mills appreciates the opportunity to offer written comments regarding the Food and Drug Administration's (FDA) study on consumer responses to Nutrition Facts labels with various footnote formats and declaration of added sugars.

General Mills Inc. (GMI) is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. General Mills is a major packaged-food manufacturer engaged for over 75 years in the development and production of food products including flour, ready-eat-cereals, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other products.

General Mills firmly believes in the value of communicating a product's nutritional attributes through various media, including food packages. We apply current regulations to ensure that all of our labels, including claims are appropriate, truthful and not misleading. In addition, we have an industry leading Consumer Insights function that focuses on keeping the voice of the consumer at the forefront of all General Mills' product and marketing decisions. We would welcome an opportunity to have further dialogue with FDA to share additional insights and expertise on the study design and questionnaire and better help the Agency meet their overall objectives.

Reducing the incidence of obesity and improving health are common goals behind public and private sector initiatives, including FDA's proposed study and potential changes to the Nutrition Facts panel (NFP). We are fully supportive of FDA's continuing efforts to provide consumers with information that assists them in making informed dietary choices and constructing healthful diets.

We appreciate FDA's effort to collect consumer information on various footnote formats before potentially proposing changes to the NFP. We disagree, however, with the overall intent of including added sugars on the NFP. Historically, FDA has based its policy on sound science. Hence, we strongly urge FDA to consider our comments before moving ahead with the proposed consumer research study.

We acknowledge that the 2010 Dietary Guidelines for Americans recommend reducing intakes of added sugars and that foods and beverages can vary widely in their contribution of added sugars to the diet. The 2010 Dietary Guidelines for Americans made seven recommendations for food/components to reduce, nine recommendations for foods/components to increase and six more recommendations to increase foods/components for specific populations. We urge FDA to prioritize these recommendations and consider making changes to the NFP that add value and educate consumers, such as making calories easier to see. FDA must carefully consider whether it should be using the limited label space on the NFP for added sugar labeling, given all of the other recommendations.

Executive Summary of General Mills' Comments:

- General Mills supports FDA conducting consumer research to gain a better understanding of how consumers use the Nutrition Facts panel, especially the utility of current footnote and additional formats. We do not support the proposed consumer research on a separate declaration of added sugars.
- While General Mills recognizes the Agency's interest in added sugars, we do not support a separate declaration of added sugars on the Nutrition Facts panel.
    - The existing scientific literature does not support a relationship between sugars or added sugars and obesity or any other chronic health conditions beyond dental caries. In addition, the body does not distinguish between added and naturally occurring sugars.
    - Current analytical methods cannot differentiate between added and naturally occurring sugars in foods, which would make it cumbersome for FDA to ensure compliance of the value listed on the NFP.
    - Labeling added sugars could create consumer confusion and lead to unintended consequences when making food choices. For many foods and beverages, total and added sugars content is nearly the same, especially given FDA's rounding rules. Therefore, we believe that a separate declaration of added sugars will not provide any additional value to consumers.
- General Mills welcomes further dialogue with FDA to share additional consumer insights and expertise into the study design and questionnaire.

Detailed GMI Comments:

1. **<u>Declaration of added sugars:</u>**

General Mills applauds FDA's efforts in helping consumers make the right food choices by using nutrition information. However, as we have noted in several previous comments to the Agency, we strongly believe that there are compelling and legitimate scientific, regulatory and consumer reasons against a separate declaration of added sugars on the NFP.

Science:

First and foremost, there is no scientific justification to support a declaration of added sugars on the nutrition label. The existing scientific literature does not support a relationship between sugars or added sugars and obesity or any other chronic health conditions beyond dental caries. After evaluating the scientific evidence, the 2010 Dietary Guidelines Advisory Committee, after, concluded that: "A moderate body of evidence suggests that under isocaloric controlled conditions, added sugars, including sugar-sweetened beverages, are no more likely to cause weight gain than any other source of energy." Thus, total calorie intake relative to energy expenditure is a critical factor in the development of obesity, rather than added sugars. In addition, the body does not distinguish between added and naturally occurring sugars. Hence, emphasizing added sugars on the NFP does not have a scientific basis.

Regulatory:

Many foods contain both added and naturally occurring sugars. Currently, FDA enforces the sugar declaration on the NFP based on analytical testing, as outlined at 21 CFR § 101.9(g). Existing analytical methods cannot differentiate between added and naturally occurring sugars in the food. This creates a challenge to quantitatively assess the amount of added sugars by the Agency to ensure regulatory compliance.

Consumer understanding:

Historically, FDA has not articulated how added sugars would be defined, measured or calculated for nutrition labeling purposes. In its planned consumer research, FDA would test terms and examples that it has not defined or justified and hence could cause potential consumer confusion. In addition, based on an assessment of General Mills' consumer inquiries, there is already adequate information about sugars on the Nutrition Facts panel for consumers. In the past three and half years (Jan 2010- June 2013), we have found that only 6 % of all the health, nutrition and wellness inquiries were about sugars in general and only a fraction of those inquiries were specific to added sugars.

One of FDA's goals is to help consumers make informed food choices. However, a separate added sugar declaration could lead to unintended consequence. For many foods and beverages, total and added sugars content is nearly the same, especially given FDA's rounding rules. Therefore, we believe that a separate declaration of added sugars will not provide any additional value or information to consumers. Consumers who might choose foods on the basis of added sugars could misconstrue the nutritional value of nutrient dense foods such as ready-to-eat cereals, flavored milks and yogurt. The 2010 Dietary Guidelines for Americans recommended limiting intake of added sugars while acknowledging their value in increasing the palatability of nutrient-dense foods, specifically whole-grain breakfast cereals and low-fat yogurt. Also, analysis of 2009-2010

NHANES data[1] (Appendix 1: Pie Chart Depicting Food Sources of Total Sugar in the US Diet), shows that ready-to-eat cereals, including those with added sugars, contribute only 3% and yogurt contributes only 2% to the total sugar consumption for the general population. Exclusion of these nutrient dense foods could result in reduced intakes of both essential vitamins and minerals and foods groups, such as whole grains and dairy. For example, a recent study[2] found that when flavored milk was eliminated from 51 elementary schools from 7 districts, elementary student milk consumption dropped dramatically, an average of 35%. Unfortunately, minor supplementation or changes of the core menu offering did not replace the essential nutrients delivered by flavored milk.

In summary, GMI strongly urges FDA to reconsider the need to conduct this consumer study on the separate declaration of added sugars, and instead recommends that FDA find ways of educating consumers on using information on the current NFP to make informed dietary choices.

2. Study Design and Questionnaire:

The overall study design and questionnaire will not adequately meet FDA's stated objectives of 1. Replacement of the existing information in the footnote area with other statements; and 2. Insertion of a separate declaration for added sugars. If FDA moves forward with the consumer study, it is imperative that the study uses sound methodology and the information generated is valid and robust to help inform FDA's future actions.

GMI has several concerns and comments on the proposed consumer study design and questionnaire. Below is an outline of our recommendations that would make the study more robust and efficient, and improve the quality of actionable results. We have provided additional details on the study design in Appendix 2 (Titled: General Mills' Detailed Recommendation for An Improved Study Design)

a. Study Design Recommendations:

The current study design does not allow researcher to distinguish between whether added sugar declaration or footnote is indeed influencing the consumer's choice. Thus, our first recommendation is that the two studies (added sugar and footnotes) be separated, and have consumers review labels with only one variable at a time, versus multiple variables. Not only will this simplify the design, it will reduce the overall number of participants needed and improve the robustness of the results. This separate study design will allow researchers to attribute the outcome to the appropriate variable and better capture the impact of consumers' understanding of a product's nutritional value.

Second, we recommend inclusion of a beverage as one of the products to be tested to see if consumers respond differently to liquid versus solid food formats. For example, we recommend replacing yogurt, a nutrient dense food that contributes calcium and vitamin D (2010 DGA

[1] Source: United States Department of Health and Human Services. Centers for Disease Control and Prevention. National Center for Health Statistics. National Health and Nutrition Examination Survey (NHANES), 2009-10.
[2] http://www.milkdelivers.org/files/resources/final-version-for-md_082510_mdp-2.pdf

nutrients of need) to the population, with a beverage comparison, such as Sport Drinks or Juice Drinks.

Third, we recommend using NFPs that are representative of real products in the marketplace for the product comparisons. The current examples provided in the test stimuli are unrealistic, and have too much disparity in their nutrient content. The extreme and unrealistic disparity, especially in the "total sugar" and "added sugar" labels will introduce bias and lead consumers to pick one product over the other. In addition to wide disparity in the "sugars" values, some of the labels also show wide and illogical variability in some of the other nutrient values. Typically in a given food category, there aren't dramatic differences in all the nutrients across products. To truly test the way consumers shop and their understanding of the nutrition label, our recommendation would be to use nutrition labels similar to what consumers see in the marketplace. For example, it would be realistic to show the cereal NFP label with milk, as that is how almost all cereals in the marketplace are labeled. In addition, the cereal comparisons must be made between products with the same reference amounts customarily consumed (RACC). Cereals with two different RACCs will have significant differences in their nutrient profiles, including calories and sugars. This is not a fair comparison and introduces an additional variable. To build on the issue of comparing completely different product profiles –comparing a Light yogurt (Yog 1) to a Regular yogurt (Yog 2 & 3) is not a fair comparison because these product categories have distinct and different consumer bases.

Fourth, we recommend that the questions be significantly reordered in the questionnaire. We propose to group all the questions showing a single label first and then test the questions with comparisons. FDA should ask the general questions around buying behavior (section F) in the beginning to remove any biases that could be introduced if consumers are shown the labels ahead of answering these questions. Also, section B should precede section A to avoid any bias resulting from beginning a test with a comparison of labels.

Fifth, we recommend eliminating Footnote 5 because it includes a dietary guidance message and is too focused on the nutrients to reduce in the diet. This type of information is not in scope and does not meet FDA's intent of understanding the use of different footnote formats and the significance of Daily Values. In addition, having the downward arrow could be confusing in instances where the level of a nutrient is already lower (e.g. low sodium products) and the product could be a good choice either for reducing that nutrient or as part of an overall diet.

Finally, we recommend not stating that the survey is on behalf of the FDA. This is a leading question, as it heightens the respondents' sensitivity as to why the test is being conducted and may influence their answers. For example, consumers may understandably want to look like "smart shoppers" in front of the FDA, and thus read the label more carefully than they normally would in the marketplace.

In summary, we believe that these recommendations will significantly improve the study design and yield more robust results to help FDA meet their study objectives.

b. <u>Study Questionnaire:</u>

General Mills is concerned that the questionnaire does not fully align with the research objectives, and that the questions are unclear, confounded and not quantitatively sensitive. It is unclear how the questions would measure comprehension of the footnotes in the NFP or variants under consideration. The questions introduce terminology that FDA has either defined differently or has yet to define. Many of the questions introduce unnecessary bias against single nutrients and do not necessarily address FDA's stated goals for the consumer study. In addition, the proposed study questionnaire is based on many assumptions and leads the consumers down a certain path, and thus would yield flawed results. Though it is not an exhaustive list, we have identified several such examples in Appendix 3 (Titled: General Mills' Recommendations to Study Questionnaire) and provided our recommendations to improve the questionnaire.

In conclusion, General Mills supports FDA's continuing efforts in providing consumers information to assist them in making informed dietary choices and constructing healthful diets. Reducing obesity and improving health are common goals behind public and private sector initiatives, including FDA's proposed study and potential changes to the NFP. However, GMI is not supportive of a separate declaration of added sugars on the NFP. For this reason, we question the need for the FDA study on declaration of added sugars. However, if the agency moves forward with the study, we strongly believe that the study design and questionnaire can be significantly improved to meet the overall objectives of the study. For the detailed reasons addressed in our comments, we urge FDA to thoroughly review and thoughtfully consider them and significantly refine the study protocol and questionnaire accordingly. We sincerely appreciate the opportunity to provide comments to FDA on this important topic. We would welcome an opportunity to partner with FDA and extend our consumer insight expertise to design a study which is robust and provides actionable results to meet the overall study objectives.

Respectfully submitted,

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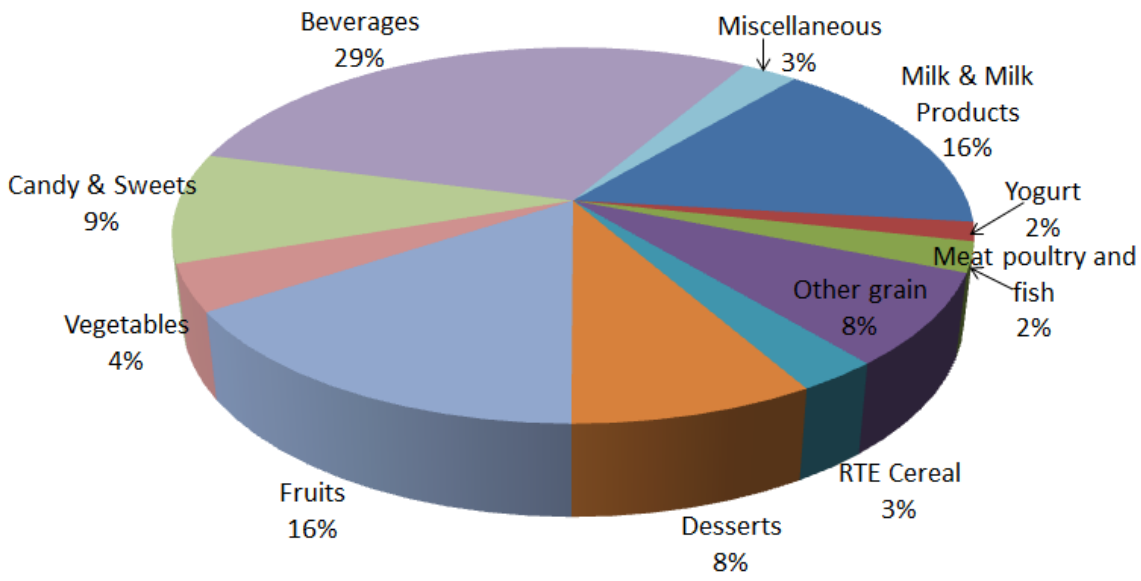
Appendix 1: Pie Chart Depicting Food Sources of Total Sugar in US Diet – Total Population Age 2+ years (NHANES 2009-2010)



Source: United States Department of Health and Human Services. Centers for Disease Control and Prevention. National Center for Health Statistics. National Health and Nutrition Examination Survey (NHANES), 2009-10.

Appendix 2: General Mills' Detailed Recommendation for an Improved Study Design

Below are recommendations from General Mills' Consumer Insights experts for an improved and efficient study design that requires fewer participants and will result in more robust data. If FDA were to adopt this new study design, the study questionnaire would need significant revision to match the study design and achieve optimal results. In summary, this study design involves consumers looking at labels with one variable at a time vs. multiple variables simultaneously. Additionally, the proposed changes provide for more robust data and a smaller sample size, which will increase the quality of the data and reduce financial burden and time. We would welcome an opportunity to have further dialogue with FDA to share additional insights and expertise into the study design and questionnaire to help meet the overall objectives of the Agency.

- To meet the objective of understanding whether the consumer would benefit from the inclusion of "added sugars" or not, General Mills' recommendation would be to use two nutrition panels, one that contains "added sugars" and one that does not. All other variables should be held constant (calories, fat, etc.). Holding all variables constant but "added sugars" allows one to know what is clearly driving differences in perception, should there be any differences at all. A monadic read is the best approach as consumers will not

have the option of viewing a panel with and without the "added sugars" line in the marketplace.

- Only if there is a meaningful difference in consumers' views based on the monadic read, then the addition of the "added sugars" line should be considered. The design would still include an element of comparison, as each person would evaluate both nutrition panels (they would be rotating – half would see the panel with added sugars first and half would see the panel without the added sugars line first). This sequential element would allow understanding if the change is noticed and if so, how it is perceived. Also, this design would produce a large enough sample size of first order reads to review the data both monadically and sequentially. Each nutritional panel would be evaluated on the key variables.
- This change in design is also a better use of the sample size. It would not require such an enormous sample size to complete, as initially proposed by FDA. In fact, this design would enable collection of more robust data by obtaining more completes per panel and since fewer panels would be needed, overall sample size would be reduced. For example, for the "added sugars" panel, one would obtain n=400 first order reads for each nutrition panel (with and without "added sugars" line). This yields n=800 completes and n=400 first order reads, which is incredibly robust. If all three categories were tested: yogurt, frozen meal, cereal, we would need n=2,400 completes.
- The footnote objective should be separated from the "added sugars" objective from a testing standpoint. It would be setup similarly to the "added sugars" test, but an incomplete block design would likely be needed to reduce respondent fatigue (e.g. each respondent would only view 2 of 6 footnotes, but all footnotes would be compared against each other). If we maintained the same robust sample, we would need n=2,400 for each category, crackers and frozen meals, or n=4,800 in total.

In conclusion, the suggested changes to the study design will result in more robust data in spite of reduction in sample size (combined sample, added sugars and footnote is n=7,200, which is much less than the 10,000 needed in the current design). In addition, reduction in sample size would result in financial savings and faster fielding time.

Appendix 3: General Mills' Recommendations to Study Questionnaire

General Mills strongly believes that the overall study design and questionnaire will not adequately meet FDA's stated objectives of 1. Replacement of the existing information in the footnote area with other statements; and 2. Insertion of a separate declaration for added sugars. If FDA moves forward with the consumer study design as is, it is imperative that the following recommendations be considered to ensure that the information generated is valid and robust to help inform FDA's future actions.

1. Section A:

GMI recommends using nutrition facts panels comparing foods from the same category and are representative of products currently in the marketplace. The current examples provided in the test stimuli are unrealistic, and have too much disparity in their nutrient content. The extreme and unrealistic disparity, especially in the "total sugar" and "added sugar" labels, introduce bias and

lead consumers to pick one product over the other. In addition to wide disparity in the "sugars" values, some of the labels also show wide and illogical variability in some of the other nutrient values. Typically in a given food category, there aren't dramatic differences in all the nutrients across products. To truly understand the way consumers shop and their understanding of the nutrition label, our recommendation would be to use nutrition labels similar to what consumers see in the marketplace. Also, for the cereal NFP, it would be realistic to show the label with milk, as that is how almost all cereals in the marketplace are labeled. To build on the issue of comparing completely different product profiles –comparing a Light yogurt (Yog 1) to a Regular yogurt (Yog 2 & 3) is not a fair comparison because these product categories have distinct consumer base. This reasoning holds true for cereal as well. When comparing cereals, comparisons must be made between products with the same reference amounts customarily consumed (RACC). Cereals with two different RACC will have significant differences in their nutrient profiles, including calories and sugars and aren't a fair comparison.

2. Section A & B:

   GMI recommends changing the terminology of the draft question A1 to exclude the term "healthier". Questions A1 and B1 assume that consumers have a common definition of what is "healthy"/"healthier" regarding a food. Consumers most likely have different definitions or perceived notions of what "healthier" means to them (e.g. organic, natural claims, less ingredients, environmentally friendly & sustainable etc.) which would skew their responses. Varying degrees of responses in the study could indicate either that, consumers do not understand the food label, or that they have different views of what constitutes a "healthy" food. Thus, asking consumers to choose which food in a pair is "healthier" is unlikely to produce clear results. Also, the word "healthier" is a synonym for "healthy" as per FDA regulations (21 CFR 101.65(d)(2)).

3. Section B:

   GMI recommends that FDA remove the term "healthy" in question B1 and also include a question seeking a rationale for understanding consumers' assigned ratings. In addition, GMI encourages FDA to consider a text highlighter that allows the respondent to indicate which parts of the label are driving the positive and negative perceptions of health. Questions B1 –B6 of the draft questionnaire assume that consumers are knowledgeable about nutrition as it relates to health outcomes and in some cases leads them to wrongly assume that a single nutrient or food could contribute to the risk of certain diseases. FDA has a specific definition for "healthy" which does not include criteria for sugars. These questions assume that consumers have a common definition for "healthy". In addition, these questions do not provide answers to nullify or prove any of the 8 hypotheses FDA is planning to test via this consumer study. As written, Question B1, regarding the relative overall healthfulness of the product reflected in the label, is subjective.

4. Questions B7 and C1-4:

GMI recommends that FDA ask consumers to provide a rationale for their responses. The questions assume that consumers will be able to accurately characterize percent daily values relative to the footnotes being tested in the variety of experimental conditions. In nutrient content claim definitions, such as those for "low fat" and "low sodium", the FDA definition is not set at 5% Daily Value. This is particularly relevant regarding the wording of question C4, as the claim

definitions of “low sodium” and “low fat,” the two descriptors in the question, are not precisely 5% Daily Value. Also FDA’s footnotes describe 5% as less or little, 20% is more or a lot. This inconsistency is confusing and concerning. There is, for instance, no correlation between FDA’s footnote descriptors and “fair source” and “poor source,” which are not defined by FDA.

5. Section D:

GMI recommends elimination of this section (questions D1-D3) since it is unclear what additional information FDA would get from these questions and how FDA would use the results.

6. Section F:

GMI recommends moving questions F1-F5 earlier in the questionnaire (e.g. move to current Section A), before they evaluate nutritional labels on products from the categories listed. Having these questions after the nutrition facts panel evaluation leads to bias. GMI recommends removing the timeframe of two weeks from question F4. This question is getting at how consumers have used the NFP to make purchase decisions and two weeks seem too short of a time frame. GMI recommends eliminating question F6 since the goal of this question, and its relationship to consumers’ use of nutrition facts panel also is not clear. This question is the only question in the study that asks about consumers’ understanding of ingredients. If this question remains in the questionnaire, we recommend significant alterations. If the purpose of this question is to ensure or gauge consumers’ understanding of added sugars, it doesn’t have to be directed to “dessert products” only. The question could read “the list below included the ingredients that might be found in several commonly consumed food products. Which of these……”. In addition, it will be helpful to gauge consumer understanding of sources of added sugars which have a positive health perception, such as agave. Also, GMI recommends adding ingredients such as table sugar, sucrose, maple syrup, and evaporated cane juice as well in the list. In addition, GMI would suggest adding an additional open ended question before this question F6 asking what they think added sugars means and what they consider added sugars to be.

7. Questions G3, G4, G5:

Questions G3-G5 do not have any bearing on the study objectives of testing footnotes and added sugar declaration. If FDA’s intent is to see if consumers are concerned about certain nutrients, GMI recommends rewording the questions G3-G5 to the following “During the past 3 months, what, if anything, have you changed to improve your diet?” In addition to limiter nutrients like fat, sodium, sugar etc., positive nutrients should also be included such as fiber, protein and vitamins. GMI also recommends elimination of “processed foods” since there is no consistent definition of “processed foods” and does not contribute to the objectives of this study.